

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

JACOBS et al.

Serial No. 09/913,954

Filed: December 4, 2001

Title: DIAGNOSTIC AND SCREENING METHOD

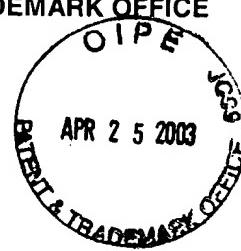
Atty Dkt. 227-142

C# M#

Group Art Unit: 1634

Examiner: S.A. Sakelaris

Date: April 25, 2003



Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

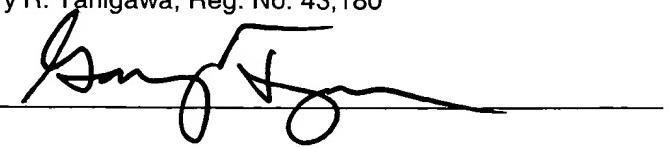
 Correspondence Address Indication Form Attached.**Fees are attached as calculated below:**

Total effective claims after amendment previously paid for	0 20	minus highest number (at least 20) =	0 x \$ 18.00	\$ 0.00
Independent claims after amendment previously paid for	0 3	minus highest number (at least 3) =	0 x \$ 84.00	\$ 0.00
If proper multiple dependent claims now added for first time, add \$280.00 (ignore improper)				\$ 0.00
Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) (\$110.00/1 month; \$410.00/2 months; \$930.00/3 months)				\$ 0.00
Terminal disclaimer enclosed, add \$ 110.00				\$ 0.00
<input type="checkbox"/> First/second submission after Final Rejection pursuant to 37 CFR 1.129(a) (\$750.00)				\$ 0.00
<input type="checkbox"/> Please enter the previously unentered , filed				
<input type="checkbox"/> Submission attached				
			Subtotal	\$ 0.00
If "small entity," then enter half (1/2) of subtotal and subtract				-\$ 0.00
<input type="checkbox"/> Applicant claims "small entity" status. <input type="checkbox"/> Statement filed herewith				
Rule 56 Information Disclosure Statement Filing Fee (\$180.00)				\$ 0.00
Assignment Recording Fee (\$40.00)				\$ 0.00
Other:				0.00
			TOTAL FEE ENCLOSED	\$ 0.00

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

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NIXON & VANDERHYE P.C.
By Atty: Gary R. Tanigawa, Reg. No. 43,180

Signature: 



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FOR: DIAGNOSTIC AND SCREENING METHOD

* * *

RESPONSE TO RESTRICTION REQUIREMENT

April 25, 2003

Hon. Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the pending Office Action (Paper No. 11) mailed March 26, 2003, entry and consideration of the following remarks are respectfully requested.

Claims 1-14 are pending. Applicants elect Group I (claims 1-10) with traverse for examination on the merits. Applicants reserve the right to prosecute nonelected subject matter in a further patent application.

Reconsideration of the restriction requirement is requested. Initially, it is noted that no lack of unity was found during the International phase of examination. Claims 1-13 were the subject of both the Int'l Search Report and the Int'l Preliminary Examination Report; claim 14 was not searched because it allegedly did not comply with PCT Art. 6.

Notwithstanding the above election, Applicants disagree with the Examiner's contention that claims 1-14 lack unity of invention, and hence require restriction into different groups of inventions. Traversal is based on the pending claims being so linked as to form a single general inventive concept under PCT Rule 13.1. Therefore, Applicants request that claims 1-14 be examined together in this application.

It was alleged on page 2 of the Office Action that each of the pending claims has been presented in improper Markush format because "distinct methods are improperly joined in the claims." Assuming arguendo that this allegation is correct, it is not the basis for finding lack of unity. The issue is whether or not the claims are so linked as to form a

single general inventive concept under PCT Rule 13.1, instead of whether or not the claims differ in scope. Of course, the scope of claims must be different because they would otherwise be rejected under Section 101 double patenting. The present claims are, however, directed to a single general inventive concept.

It was further alleged on pages 2-3 of the Office Action that the claims are distinct because

both the mutation or mutations in the nucleic acids of group I, the mutant form of Group II, and the POLG gene of group IV being analysed in the methods, comprise a distinct structure and as a whole each biomolecule is functionally distinct over each other. Additionally, the kit of Group III is different in composition and does not include the same process steps as those involved in the method groups. Each group has a different special technical feature. As the claimed methods and kit all use analysis with different polynucleotides, they do not share a special technical feature.

The Examiner contends that the inventions listed as Groups I-II and IV do not relate to a single general inventive concept because they lack the same or corresponding special technical features. But here, the special technical feature linking claims 1-14 is that "a mutation or mutations in the POLG gene encoding mitochondrial DNA polymerase" can be used "for the detection of infertility in males" (see Abstract of the Disclosure). The mutation(s) of the POLG gene (claims 1-10), mutant form(s) of the POLG gene (claims 11-12), and the POLG gene used as an indicator (claim 14) are all aspects of this special technical feature. While POLG mutations arguably have distinct structures, they are directed to the same concept (i.e., "special technical feature"). They are also directed to the same objective: diagnosis or prediction of infertility.

Furthermore, Applicants submit that the claims identified by the Examiner as Groups I and III are linked to form a single general inventive concept in accordance with the M.P.E.P. In particular, the Examiner's attention is directed to M.P.E.P. § 1850 C. Combinations of Different Categories of Claims (8th Ed., August 2001) which states on page 1800-62:

The method for determining unity of invention under Rule 13 PCT shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(B) In addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process

Also an apparatus or means shall be considered to be specifically designed for carrying out a claimed process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art. Consequently, it would not be sufficient that the apparatus or means is merely capable of being used in carrying out the claimed process. However, the expression specifically designed does not imply that the apparatus or means could not be used for carrying out another process, nor that the process could not be carried out using an alternative apparatus or means.

In accordance with the section of the M.P.E.P. quoted above, claims 1-12 and 14 are directed to a process of diagnosis/prediction and claim 13 is directed to a kit which is "specifically designed" for carrying out that process.

At a minimum, Applicants submit that there is no lack of unity between claims 1-10 (i.e., methods of diagnosis) and claim 13 (i.e., diagnostic kits). It is therefore believed that even if the Examiner maintains that the methods of Groups I-II and IV lack unity of invention, claim 13 should be examined with the elected method claims because it is directed to a diagnostic kit specially designed to carry out the process of claims 1-10.

If this requirement is not withdrawn such that claims 1-10 and 13 are searched and examined in this application, the Examiner is respectfully requested to address with particularity why the requirements of M.P.E.P. § 1850 C do not apply in this application.

Applicants earnestly solicit an early and favorable examination on the merits. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By:


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